Standard Operating Procedure

SUBJECT: Develop and Maintain Standard Operating Procedures for the caBIG™ Program	SOP No.: AD-001
	Version No.: 2.0
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Standard Operating Procedure –

Developing and Maintaining Standard Operating Procedures under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

Issued Date: October 30, 2006

Effective Date: December 11, 2006

Department Approval:

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Peter Covitz

Chief Operating Officer, NCICB

QA Approval:

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George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	9/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.

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1. Purpose

This Standard Operating Procedure (SOP) describes the process for the development and maintenance of SOPs at intramural and extramural sites under the caBIG™ umbrella.

2. Scope

This SOP will be used as guidance for the development and maintenance of all SOPs related to: a) research covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI), and b) the sharing of data across caBIG™ participant sites, the regulatory community and commercial industry.

3. Requirements

3.1 All SOPs will be developed, maintained, and updated in compliance with this SOP and the SOP template approved by the National Cancer Institute Center for Bioinformatics (NCICB) and the SOP Working Group under the CTMS Best Practice Special Interest Group (SIG).

3.2 SOP Working Group participants will have input into the development of SOPs.

3.3 Participating sites under caBIG™ Program will use the SOP for guidance. The SOP will be approved by NCICB and the SOP Working Group before the SOP is operational. Any changes that need to be made to the SOP for site-specific purposes should be incorporated as an "Attachment" to the SOP.

3.4 Before an SOP becomes operational, the SOP shall be distributed to all participating sites and training shall be completed for all appropriate staff.

3.5 Changes to the SOP must be in compliance with the *SOP for Deviations and Revisions*.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	N/A	International Conference on Harmonization; Good Clinical Practice Guidelines, E6, Section 1.55
4.3	N/A	21 CFR 312.60 General Responsibilities of Investigators
4.4	AD-002	SOP for Managing Deviations and Revisions to SOPs
4.5	AD-003	SOP for Release and Distribution of SOPs

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5. Roles & Responsibilities

Role	Responsibility
SOP Author	- Obtain unique SOP number. - Supply Title/Subject. - Prepare draft SOP stating in general terms the information necessary to provide guidance on performing a job function or task, and identify the individuals responsible for each action. - Supply Author's Name and Title. - Supply Approver's Name and Title. - Supply Authorizer's Name and Title.
NCICB QA Officer	- Ensure SOP numbering system is consistent and in specified format. - Review final SOP for Quality Control of SOP formatting. - Maintain a record of final approval dates and versions. - Distribution of SOP and subsequent document control. - Ensure that all necessary training for SOP is provided and completed prior to SOP becoming operational. - Conduct annual review of SOPs in accordance with NCI policy, unless otherwise noted in the SOP. - Sign-Off on SOP – indicating that the SOP complies with NCI policy, and applicable SOPs for creating and maintaining SOPs.
SOP Working Group	- Identify priority for development of SOPs. - Review and Approve final draft of SOP. - Conduct annual review of SOPs.
NCICB Applications Director	Sign-Off of SOP – indicating that the NCICB and the SOP Working Group has approved the SOP.
NCICB Technical Officer	- Upload approved SOPs onto caBIG™ website. - Provide troubleshooting support for accessing and downloading approved SOPs.
Document Officer	- Notify all caBIG™ adopters of new SOP posting. - Manage SOPs, including some version control of SOPs and establishing methods to organize SOPs for easy access.

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6. **Attachments**	

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Developing and Maintaining SOPs	This document provides instructions for the preparation of SOPs and it establishes procedures and responsibilities to ensure that all SOPs are prepared, retained and deleted in a consistent manner.
	The content of this procedure should be followed strictly; any departure from this procedure should be documented and brought to the attention of senior clinical staff at the site.
2) Principles for Writing SOPs	Outline of best practices for developing SOPs
3) Process Flow for Developing and Maintaining SOPs	This document graphically depicts the work flow activities, by role, that are performed in the process for developing and maintaining SOPs.